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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2003D–0232]

Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices" (validation data guidance). The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), added a section to the act to establish new regulatory requirements for reprocessed single-use devices (SUDs). MDUFMA was signed into law on October 26, 2002. One requirement of the new provision is the submission of validation data for certain class I and II reprocessed SUDs. This guidance document is intended to assist manufacturers of reprocessed SUDs in understanding and complying with this new MDUFMA requirement. The new section of MDUFMA establishes requirements applicable only to reprocessed SUDs.

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled "Guidance for Industry and FDA Staff; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4692.

SUPPLEMENTARY INFORMATION:

I. Background

Section 302(b) of MDUFMA adds new requirements for reprocessed SUDs to section 510 of the act (21 U.S.C. 360). One of MDUFMA's provisions requires the submission of validation data specified in the statute for certain reprocessed SUDs (as identified by FDA). The types of validation data include cleaning and sterilization data, and functional performance data.

MDUFMA requires that FDA review the types of reprocessed SUDs now subject to premarket notification requirements and identify which of these devices require the submission of validation data to ensure their substantial equivalence to predicate devices. MDUFMA also requires that FDA review critical and semicritical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices requires the submission of 510(k)s to ensure their substantial equivalence to predicate devices. Under MDUFMA, the validation data submitted for a reprocessed SUD must demonstrate that the device will remain substantially equivalent to its predicate after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

MDUFMA required that FDA publish two lists in the **Federal Register** by April 26, 2003, concerning the following: (1) A list of critical reprocessed SUDs whose exemption from 510(k) requirements will be terminated, and (2) a list of reprocessed SUDs that are currently subject to 510(k) requirements for which validation data must be submitted. FDA will update these lists as necessary. MDUFMA specifies timeframes during which the validation data must be submitted for reprocessed SUDs on these lists. This guidance document describes the types of validation data that FDA recommends these submissions include. Additionally, the guidance explains the effect of the validation data requirement on reprocessed SUDs that had been cleared, or had applications pending, before the publication of the lists.

FDA is implementing this level 1 guidance document upon issuance because it is essential for the agency to provide immediate guidance on the validation data required by MDUFMA. Under MDUFMA, manufacturers of reprocessed SUDs have a limited time period during which they can develop

and submit this validation data. The agency has determined, in light of the need to provide immediate guidance to these manufacturers, that a request for comments before issuance of this guidance is not feasible. The data submission recommendations set forth in this guidance will become effective immediately after approval by the Office of Management and Budget (OMB) of the collection of information proposed by FDA in this guidance. In developing this guidance, the agency has considered comments on the topic that were submitted to the public docket on MDUFMA implementation, docket number 02N–0534.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on validation data regarding the cleaning, sterilization, and functional performance of reprocessed SUDs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the contact person (see **FOR FURTHER INFORMATION CONTACT**).

The guidance provides information on the validation data for reprocessed SUDs required by MDUFMA. In some cases, FDA may have already published product-specific guidance, other relevant guidance that applies to the same type of device, or guidance that is generally applicable to premarket submissions. MDUFMA and this validation data guidance supersede any existing guidance that recommends less complete data and information than described in this validation data guidance.

III. Electronic Access

To receive "Guidance for Industry and FDA; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices" by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1216) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This notice and the guidance entitled "Guidance for Industry and FDA; Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use

Medical Devices" contain a proposed collection of information that requires clearance by OMB under the Paperwork Reduction Act of 1995. In a document published elsewhere in this issue of the **Federal Register**, FDA is announcing that this proposed collection of information has been submitted to OMB for emergency processing. The notice also solicits comments concerning the proposed collection of information.

FDA will publish a separate notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions contained in this notice and the guidance. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

V. Comments

You may submit written or electronic comments regarding this guidance to the Division of Dockets Management (see **ADDRESSES**). You should submit two copies of a written comment or one copy of an electronic comment. Individuals may submit one copy of a written comment. You should identify comments with the docket number found in brackets in the heading of this document. The guidance document and comments are available in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/27/03
June 27, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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